

(ii) Send a paper Form FDA 3942b to the U.S. Food and Drug Administration (HFS-681), 5100 Paint Branch Pkwy., College Park, MD 20740. We recommend that you submit a paper copy only if your facility does not have reasonable access to the Internet.

(c)(1) A facility must determine and document its status as a qualified facility on an annual basis no later than July 1 of each calendar year.

(2) The attestations required by paragraph (a) of this section must be:

(i) Submitted to FDA initially:

(A) By *December 16, 2019* for a facility that begins manufacturing, processing, packing, or holding animal food before *September 17, 2019*;

(B) Before beginning operations, for a facility that begins manufacturing, processing, packing, or holding animal food after *September 17, 2019*; or

(C) By July 31 of the applicable calendar year, when the status of a facility changes from “not a qualified facility” to “qualified facility” based on the annual determination required by paragraph (c)(1) of this section; and

(ii) Beginning in 2020, submitted to FDA every 2 years during the period beginning on October 1 and ending on December 31.

(3) When the status of a facility changes from “qualified facility” to “not a qualified facility” based on the annual determination required by paragraph (c)(1) of this section, the facility must notify FDA of that change in status using Form FDA 3942b by July 31 of the applicable calendar year.

(d) When the status of a facility changes from “qualified facility” to “not a qualified facility,” the facility must comply with subparts C and E of this part no later than December 31 of the applicable calendar year unless otherwise agreed to by FDA and the facility.

(e) A qualified facility that does not submit attestations under paragraph (a)(2)(i) of this section must provide notification to consumers as to the name and complete business address of the facility where the animal food was manufactured or processed (including the street address or P.O. Box, city, state, and zip code for domestic facilities, and comparable full address infor-

mation for foreign facilities) as follows:

(1) If an animal food packaging label is required, the notification required by paragraph (e) of this section must appear prominently and conspicuously on the label of the animal food.

(2) If an animal food packaging label is not required, the notification required by paragraph (e) of this section must appear prominently and conspicuously, at the point of purchase, on a label, poster, sign, placard, or documents delivered contemporaneously with the animal food in the normal course of business, or in an electronic notice, in the case of Internet sales.

(f)(1) A qualified facility must maintain those records relied upon to support the attestations that are required by paragraph (a) of this section.

(2) The records that a qualified facility must maintain are subject to the requirements of subpart F of this part.

[80 FR 56337, Sept. 17, 2015, as amended at 81 FR 3717, Jan. 22, 2016]

§ 507.10 Applicability of subparts C and E of this part to a facility solely engaged in the storage of unexposed packaged animal food.

(a) Subparts C and E of this part do not apply to a facility solely engaged in the storage of unexposed packaged animal food that does not require time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens.

(b) A facility solely engaged in the storage of unexposed packaged animal food, including unexposed packaged animal food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens is subject to the modified requirements in § 507.51 for any unexposed packaged animal food that requires time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens.

§ 507.12 Applicability of this part to the holding and distribution of human food by-products for use as animal food.

(a) Except as provided by paragraph (b) of this section, the requirements of this part do not apply to by-products of